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Registration Decision

1-Methylcyclopropene

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Table of Contents

Registration Decision for 1-methylcyclopropene 1
What Does Health Canada Consider When Making a Registration Decision? 1
What is Compound 1-Methylcyclopropene? 2
Health Considerations 2
Environmental Considerations 4
Value Considerations 4
Measures to Minimize Risk 5
Other Information 5

References 7

Registration Decision for 1-methylcyclopropene

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of technical grade active ingredient 1-methylcyclopropene (1-MCP) Technical and the end-use product SmartFresh Technology to slow senescence and maintain firmness of apple fruit following harvest.

An evaluation of available scientific information found that, under the approved conditions of use, the end-use product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1]: Proposed Registration Decision, *1-methylcyclopropene* (PRD2007-11). This Registration Decision[2] describes this stage of the PMRA's regulatory process for 1-methylcyclopropene and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2007-11. This decision is consistent with the proposed registration decision stated in PRD2007-11.

For more details on the information presented in this Registration Decision, please refer to Proposed Registration Decision PRD2007-11, *1-methylcyclopropene*, which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration[3]. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act*"...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigourous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in both humans (e.g. children) and organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the PMRA's website at www.pmra-arla.gc.ca.

What is Compound 1-Methylcyclopropene?

1-Methylcyclopropene is a plant growth regulator that inhibits ethylene. It is applied to apples in airtight rooms shortly after harvest to prolong storage life. The inhibition of ethylene action and synthesis delays the onset of the climacteric period of fruit ripening in which ethylene production and respiration increase rapidly. The maturation of the fruit is delayed with the result that fruit remains firmer for a longer period.

Health Considerations

Can Approved Uses of 1-Methylcyclopropene Affect Human Health?

Potential exposure to 1-methylcyclopropene may occur through diet (food and water) or when handling and applying the product. When assessing health risks, two key factors are considered: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when using 1-methylcyclopropene products according to label directions.

The technical grade active ingredient 1-methylcyclopropene and the end-use product SmartFresh Technology did not exhibit any adverse affects in the acute studies. Consequently, no label statements are required. 1-Methylcyclopropene was not genotoxic, and there was also no indication that 1-methylcyclopropene caused damage to the nervous system. The technical grade active ingredient is a gas and no long-term exposure is expected. Subsequently, no long-term studies were conducted. The first signs of toxicity in animals given daily doses of 1-methylcyclopropene over longer periods of time were effects on the spleen, liver and kidneys. The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

When 1-methylcyclopropene was given to pregnant animals, no effects were observed on the developing fetus, young animals or the mothers. This indicates that the fetus or young animals were not more sensitive than the mothers and specific protection is not required in the risk assessment.

Residues in Water and Food

Dietary risks from food and water are not of concern.

1-Methylcyclopropene is a volatile gas and all matrices measured (including stored apples) had no measurable residues. The use of SmartFresh Technology (containing 3.3% w/w 1-methylcyclopropene) as a postharvest treatment to delay the ripening of mature stored apples does not pose an unacceptable dietary risk to any segment of the population, including infants, children, adults and seniors. There is negligible concern regarding the 3-chloro-2-methylpropene (CMP) impurity as the level in the end-use product is very low (0.000561%).

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Residue trials conducted in sealed treatment chambers using SmartFresh Technology containing 1-methylcyclopropene on apples were sufficient to propose an MRL. This MRL can be found in the Science Evaluation section, Appendix I, of the consultation documents Proposed Registration Decision PRD2007-11, *1-methylcyclopropene*.

Occupational Risks From Handling SmartFresh Technology

Occupational risks are not of concern when SmartFresh Technology is used according to label directions, which include protective measures.

During early re-entry to treatment areas, individuals can come in direct contact with 1-methylcyclopropene through inhalation of vapours or by skin contact with vapours. For this reason, the label specifies that anyone re-entering treatment areas early must wear long-sleeved shirts, long pants and chemical-resistant gloves as well as respiratory protection. In taking into consideration these requirements and the expected brief occupational exposure, risk to commercial applicators or workers is not a concern.

For bystanders, exposure is expected to be much less than that of commercial applicators and is considered negligible. Therefore, risks to bystanders are not of concern.

Environmental Considerations

What Happens When 1-Methylcyclopropene Is Introduced Into the Environment?

1-Methylcyclopropene is used indoors, and is not persistent in the terrestrial and aquatic environment once vented to the atmosphere. Thus, the risk to terrestrial and aquatic organisms is expected to be negligible.

1-Methylcyclopropene is a gas used indoors as a postharvest treatment on apples; therefore, there will be no exposure to the environment during use. However, exposure will occur once treatment rooms are vented after use. The maximum concentration of 1-methylcyclopropene in air would be 1 ppm after venting based on the maximum application rate, applied once per year in a closed apple storage facility in late summer (August to October). Once vented, the primary route of transformation of 1-methylcyclopropene gas will be via reactions with ozone, hydroxyl radicals and photolysis. Based on its short half-life (up to 4.4 hours), its vapour state and time of venting release (August to October when birds are no longer nesting and foraging activity of beneficial insects has decreased), 1-methylcyclopropene is expected to pose negligible risk to aquatic and terrestrial organisms.

Value Considerations

What Is the Value of SmartFresh Technology?

A single postharvest application of SmartFresh Technology to apples slows loss of firmness by delaying fruit ripening and senescence, and reduces the incidence of superficial scald, a physiological skin disorder, following removal from storage. As a result, use of SmartFresh Technology maintains fruit quality and extends the marketability period of apple fruit destined for either domestic or export market channels.

1-Methylcyclopropene is the first plant growth regulator registered for postharvest use on apples. The only alternative product registered to delay apple maturity and maintain fruit quality is ReTain Plant Growth Regulator (Registration Number 25609), with the active ingredient aminoethoxyvinylglycine hydrochloride (15% guarantee). ReTain Plant Growth Regulator is mainly marketed for use on apple trees to control preharvest fruit drop, with the secondary claims that it "may also delay fruit maturity, help maintain fruit quality (e.g. firmness) and may reduce the incidence and/or severity of watercore". ReTain Plant Growth Regulator is applied four weeks before the anticipated harvest date and, therefore, has a different use pattern than SmartFresh Technology.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of SmartFresh Technology to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

- **Human Health**

As there is a concern with workers coming into direct contact with 1-methylcyclopropene through inhalation of vapours or by skin contact with vapours, anyone re-entering treatment areas prior to the completion of ventilation must wear long-sleeved shirts, long pants and chemical-resistant gloves as well as respiratory protection.

Other Information

The relevant test data on which the decision is based (as referenced in this document) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision document. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Requesting a Reconsideration of Decision, www.pmra-arla.gc.ca/english/pubreg/reconsideration-e.html) or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

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[5] As per subsection 35(1) of the *Pest Control Products Act*.

References

A. LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

5.0 Value

PMRA 1116725 2005. SmartFresh Concentration Comparisons and Long-Term Commercial Trials of Apples. Final Report. DACO: 10.2.3.3,10.2.3.4

PMRA 1116726 2005. Analysis and Conclusions From Study "SmartFresh Concentration Comparisons and Long Term Commercial Trials of Apples". DACO: 10.2.3.3,10.2.3.4